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DOI:

[10.1177/0269215515576811](https://doi.org/10.1177/0269215515576811)

Document Version

Peer reviewed version

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Citation for published version (APA):

Jepson, P. A. U. L., Sands, G., Beswick, A. D., Davis, E. T., Blom, A. W., & Sackley, C. M. (2016). A feasibility randomised controlled trial of pre-operative occupational therapy to optimise recovery for patients undergoing primary total hip replacement for osteoarthritis (PROOF-THR). *Clinical Rehabilitation*, 30(2), 156-166.
<https://doi.org/10.1177/0269215515576811>

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A feasibility randomised controlled trial of pre-operative occupational therapy to optimise recovery for patients undergoing primary total hip replacement for osteoarthritis: (PROOF-THR)

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Keywords: Activities of Daily Living, Prostheses, Occupational therapy, Pre-habilitation, Osteoarthritis

Abstract

Objective: To assess the feasibility of a pre-operative occupational therapy intervention for patients undergoing primary total hip replacement.

Design: Single blinded feasibility randomised controlled trial, with data collection prior to the intervention, and at 4, 12, and 26 weeks following surgery.

Setting: Recruitment from two NHS orthopaedic outpatient centres in the West Midlands, UK.

Subjects: Patients awaiting primary total hip replacement due to osteoarthritis were recruited. Following pre-operative assessment, patients were individually randomised to intervention or control by a computer-generated block randomisation algorithm stratified by age and centre.

Interventions: The intervention group received a pre-surgery home visit by an occupational therapist who discussed expectations, assessed home safety, and provided appropriate adaptive equipment. The control group received treatment as usual.

Outcomes: The study assessed the feasibility of recruitment procedures, delivery of the intervention, appropriateness of outcome measures and data collection methods. Health related quality of life and resource use were recorded at 4, 12 and 26 weeks.

Results: 44 participants were recruited, 21 were randomised to the occupational therapy intervention and 23 to usual care. Analysis of 26 week data included 18 participants in the intervention group and 21 in the control. The intervention was delivered successfully with no withdrawals or crossovers; 5/44 were lost to follow-up with further missing data for participation and resource use.

Conclusions: The feasibility study provided the information required to conduct a definitive trial. Burden of assessment would need to be addressed. A total of 166 patients would be required in a fully powered trial.

Trial registration: ISRCTN38381590 (assigned 06/02/2012)

Introduction

Total hip replacement is considered one of the greatest successes of medical care^[1]. However, restoration of mobility and activity can take anything from one to two years, even in the total absence of pain^{[2][3]}, and 14-36% of patients may have no functional improvement 12 months after total hip replacement^[4]. The health benefits of mobility are evident in many medical conditions^[5] and functional decline in activities of daily living (ADL) due to relatively short periods of reduced activity in the older person is well documented^{[6][7]}. The typical stay for total hip replacement of three to five days has mitigated against complications and functional decline due to inactivity^[8]. However, with no routine rehabilitation provided in the UK^[9] the emphasis is on the patient to get back to functional activities as soon as possible after discharge home. This may contribute to the sub optimal recovery rates.

Occupational therapists use interventions designed to help people improve their mobility and return to activities of daily living at home or at work^[10]. Following total hip replacement, occupational therapy generally aims to improve function and prevent dislocation. Intervening prior to surgery in the patient's own home may help patients to better prepare for surgery, hospital discharge^[11] and ultimate recovery. Yet, according to a recent survey of 174 occupational therapists across the UK, the majority of services did not routinely carry out either preoperative (70%) or postoperative (94%) home visits^[12]. There is evidence to suggest that home environment modifications and adaptive devices for older people can slow the rate of functional decline^[13], decrease difficulty and increase safety of activities of daily living^[14], and reduce certain in home care costs^[13]. Additionally, a Cochrane review reported that home safety assessment and modification interventions were effective in reducing falls, especially when delivered by occupational therapists^[15]. Although this demonstrates positive impacts of

occupational therapy interventions with older people in general, there is little evidence relating to the pre-operative provision of therapy to patients undergoing hip replacements. The pre-operative domiciliary provision of assessment, advice, and appropriate adaptive equipment may enhance activity and mobility recovery.

The aim of this study was to assess the feasibility of conducting a large scale randomised controlled trial to investigate the clinical effectiveness and cost effectiveness of a pre-surgery home based occupational therapy intervention versus usual care. The outcomes measured were in accordance with guidelines produced by the Medical Research Council^[16]:

- To gain information on patient eligibility, recruitment and retention
- To assess the feasibility and acceptability of the occupational therapy intervention and the usual care control
- To determine the suitability and completeness of the outcome measures including resource use

Methods

This feasibility study was a single blind randomised controlled trial, with randomisation at the level of the individual, conducted between May 2012 and January 2013. The study took place at two National Health Service hospitals in the West Midlands, UK. Participants were identified prior to surgery from pre-operative appointments and followed up for a period of six months post-surgery. Participants were asked to complete a series of self-report questionnaires measuring activity, societal participation and resource use.

Following consultation at an outpatient clinic with an orthopaedic surgeon, the records of patients listed for a primary total hip replacement were screened by research nurses against

the inclusion and exclusion criteria to confirm eligibility. Eligible patients were then sent a study information pack which contained a letter of invitation to join the study, the patient information leaflet, and copy of the consent form. One week after posting this information, potential participants were contacted by a research nurse to ask if they would consider taking part in the study. Patients that expressed an interest in participating were approached by a member of the research team when they attended their pre-assessment clinic. Potential participants were given time to discuss any issues or concerns they may have had prior to obtaining informed consent. Participants who did not use English as their first language were given a covering letter in their own language to invite them to take part. However, the assessments needed to be carried out using the English versions with the help of a relative or friend. Participants who were unable to do this were excluded as many of the outcome questionnaires were not validated in other languages. The patient's General Practitioner was informed of the patient's participation in the trial in writing, with the patient's consent.

The Inclusion criteria were:

- Patients listed for primary unilateral total hip replacement following review in orthopaedic clinic
- Osteoarthritis as the primary indication for surgery
- No previous lower limb joint replacement surgery
- No planned additional lower limb joint replacement surgery within 12 months
- Sufficient understanding of English to complete questionnaires (or proxy completion by representative with sufficient English)

Exclusion criteria were:

- Inflammatory arthritis
- Primary indication for surgery was for pain relief only
- Patients who were unable to provide informed consent

Following baseline assessment, participants were randomised between the two groups (50:50) using a random assignment computer algorithm. A block allocation sequence was used with stratification by hospital site and age (under 65 years; 65 years and older). Randomisation was conducted by the Primary Care – Clinical Research Trials Unit based at the University of Birmingham. Allocation was revealed to the treating therapist by an independent person in the clinical trials unit. The Primary Care Clinical Research Trials Unit have developed standard operating procedures to preserve blinding in rehabilitation trials which were followed by all members of the research team. All investigators, including the trial statistician were blind to the randomisation and to any information indicating assignment. Guidelines for improving blinding in complex clinical trials were also adhered to^[17]. Ethical approval for this study was obtained from the National Research Ethics Service Committee, West Midlands – Solihull (Reference 11/WM/0162).

Patients randomised to ‘treatment as usual’ arm of the study received the usual NHS care provided to all patients undergoing elective total hip replacement in the NHS hospital where they received surgery. At both NHS hospital locations, the occupational therapists provided adaptive equipment post-surgery which is usual UK practice. Both hospitals also provided a pre-surgery multidisciplinary education package given at the hospital. Patients randomised to the intervention arm of the study were visited by an occupational therapist prior to surgery. The occupational therapist delivered an intervention package which included the provision of adaptive equipment required by the participant and education on how the equipment should

be used. The occupational therapist discussed the participant's expectations and anxieties they (and their carer) may have had; gave explanations about the surgery, hospital stay and post-operative in-patient rehabilitation; and discussed in depth with the participant how they planned to recover when they returned home. In addition, the occupational therapist explained how the layout of the participant's home might need temporarily adapting to reduce the chance of accidental dislocation risk and falls. A structured home safety assessment was performed by the occupational therapist, based on the Westmead Home Safety Assessment Form^[18]. Apart from the additional domiciliary occupational therapy intervention, all participants received the usual care pathways provided followed by the hospital, including the pre-surgery multidisciplinary education session.

Follow-up assessments were completed at 4, 12 and 26 weeks after their date of surgery by means of self-completed questionnaires mailed to the participants with pre-paid return envelopes. In the case of non-response, participants were resent the questionnaire and then telephoned a reminder. At the 26 week time point telephone follow-ups were attempted with non-responders to obtain a minimum data set. The questionnaire pack contained seven validated self-completed questionnaires. Pain, function and societal participation were measured using the updated Oxford Hip Score (OHS)^{[19][20]}; the Western Ontario and McMaster Universities Arthritis Index (WOMAC)^[21] with the data transformed to give a score 0 to 100^[22]; The Aberdeen Impairment, Activity limitation and Participation Restriction measure^[23]; the Hospital Anxiety and Depression Scale (HADS)^[24]; and the Nottingham Extended Activities of Daily Living (NEADL)^[25] questionnaire. Health related quality of life was measured using both the Euro-Qol EQ-5D-3L^{[26][27]} and the ICECAP-O^{[28][29]}. At the final 26 week time point only, an adapted Client Service Receipt Inventory (CSRI)^[30] was used to

record the frequency and duration with which participants used health and social care services over the duration of the assessment period.

Results

The CONSORT diagram shown in Figure 1 details the participant pathway through the trial.

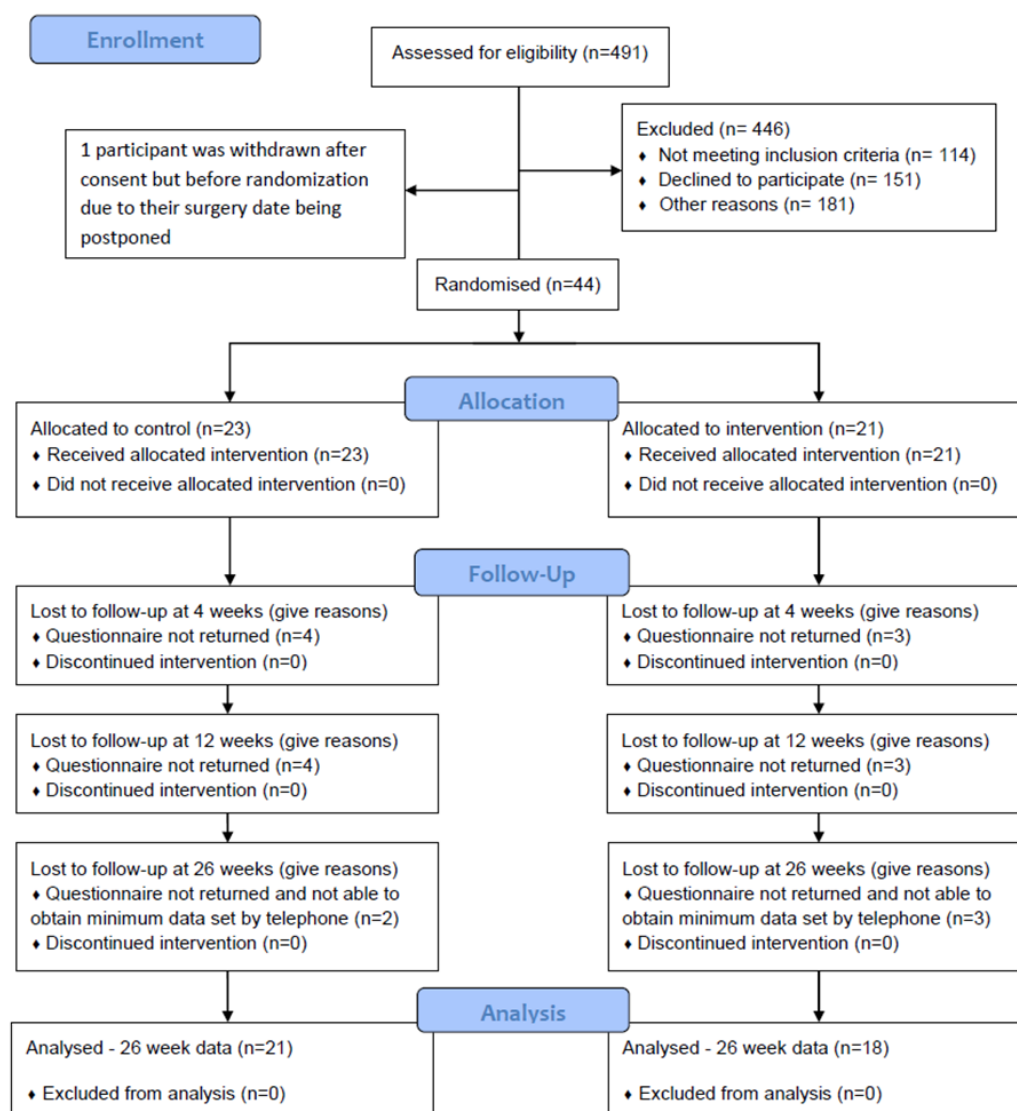


Figure I. CONSORT diagram.

Baseline participant demographics are shown in Table 1. The mean age at the time of surgery was consistent across the two groups. There were more males 24 (54%) than females 20 (46%) overall, but this varied between the intervention which had twice as many males, 14 (66%) as females, 7 (34%), and the control which had 10 (43%) males and 13 (57%) females. There was also a disparity between groups for the number of people living alone with only 1 (5%) in the intervention group, and 5 (22%) in the control group.

	Overall n=44	Allocated to intervention n=21	Allocated to usual care control n=23
Mean age at surgery (SD)	66 (10.8)	67 (11.2)	65 (10.7)
Male : Female	24 : 20	14 : 7	10 : 13
Lives alone	6	1	5
Median (range) time from consent to surgery (days)	21 (3 -372)	20 (3 – 211)	22 (5 -372)

Table 1– Patient demographics

Forty four participants completed the baseline questionnaire, the retention rates and full completion rates for each of the follow up periods, and the Client Service Receipt Inventory form (sent at 26 weeks), are presented in Table 2. The retention rate remained consistent throughout the study period, with 39 (88%) of the participants retained after 26 weeks for the follow-up questionnaire, although the Client Service Receipt Inventory return rate was slightly lower with only 31 (70%) forms returned, despite being sent with the 26 week questionnaire. Although the number of fully complete returned questionnaires was good at

baseline and reasonable at 26 weeks, completion rates were low in weeks 4 and 12, and for the Client Service Receipt Inventory questionnaire (<50% complete).

	Baseline	4 Week	12 Week	26 Week	26 Week (CSRI)
Data collected	44 (100%)	37 (84%)	37 (84%)	39*(88%)	31 (70%)
Fully completed questionnaires returned	33 (75%)	13 (35%)	18 (49%)	23 (64%)	15 (48%)

* Including telephone collected minimum data set (n=3)

Table 2 Retention and follow-up data

Table 3 presents the distribution of missing (non-answered) questions for each scale used in the study for each time point. Missing data are most prevalent in the Western Ontario and McMaster Universities Arthritis Index (122 total missing items) and Nottingham Extended Activities of Daily Living (105 total missing items). The 4 week returned questionnaires are the greatest contributor, accounting for more than half of the missing Western Ontario and McMaster Universities Arthritis Index and Nottingham Extended Activities of Daily Living data. Questionnaires with the least missing data were observed in the Baseline (54 total missing items) and 26 week (35 total missing items) follow-ups.

Questionnaire (Total no. of questions)	Baseline Missing	4 Week Missing	12 Week Missing	26 Week Missing	Total Missing
WOMAC (24)	14	66	30	12	122
OHS (12)	3	8	2	1	14
Aberdeen I (9)	4	5	1	1	11
Aberdeen A (17)	9	26	21	3	59
Aberdeen P (9)	0	3	0	1	4
NEADL (20)	21	59	13	12	105

HADS A (7)	2	2	0	0	4
HADS D (7)	1	2	0	0	3
EQ5D (6)	0	8	0	4	12
ICECAP (5)	0	6	0	1	7
Total	54	185	67	35	341

Table 3 Missing data items by scale

Table 4 presents the descriptive statistics for the pain and functional sections of the questionnaire comprising the Western Ontario and McMaster Universities Arthritis Index, Oxford Hip Score, Aberdeen Impairment, Activity limitation and Participation Restriction measure, Nottingham Extended Activities of Daily Living measure, and Hospital Anxiety and Depression Scale (Anxiety and Depression). Data for each scale showed improvement at 4 weeks, apart from the Nottingham Extended Activities of Daily Living scale which showed improvement at 12 weeks. Improvement then continued to 26 weeks.

Scale (Scale Range)	Baseline Mean			12 Week Mean			26 Week Mean		
	Overall (SD)	Control (SD)	Intervention (SD)	Overall (SD)	Control (SD)	Intervention (SD)	Overall (SD)	Control (SD)	Intervention (SD)
WOMAC (0*-100)	59.13 (17.47)	61.41 (18.32)	56.50 (16.51)	23.93 (19.09)	20.91 (14.88)	26.27 (21.96)	13.31 (14.32)	15.67 (16.60)	9.95 (9.86)
OHS (0-48*)	17.85 (7.32)	17.00 (6.28)	18.79 (8.38)	35.57 (9.69)	36.42 (7.94)	34.68 (11.42)	40.43 [†] (7.43)	39.03 (8.33)	41.28 [†] (6.16)
Ab I (9*-45)	31.62 (7.42)	32.04 (6.15)	31.13 (8.79)	16.21 (6.44)	15.21 (4.66)	17.26 (7.91)	14.71 (5.51)	15.46 (6.41)	13.67 (3.89)
Ab A (17*-85)	50.78 (14.15)	52.98 (13.82)	48.48 (14.46)	28.92 (12.57)	27.06 (8.75)	30.78 (15.53)	25.24 (8.43)	27.00 (9.53)	22.79 (6.09)
Ab P (9*-45)	21.57 (7.31)	22.83 (6.36)	20.19 (8.17)	13.43 (6.78)	12.00 (3.73)	14.94 (8.82)	11.47 (3.63)	11.57 (3.08)	11.33 (4.41)
NEADL (0-66*)	48.32 (12.46)	49.26 (10.32)	47.28 (14.67)	52.09 (17.34)	55.44 (9.87)	48.54 (22.56)	59.63 (13.04)	57.34 (16.18)	62.53 (6.95)
HADS A (0*-21)	6.63 (4.89)	6.56 (4.58)	6.71 (5.33)	3.27 (4.07)	2.68 (2.65)	3.89 (5.19)	3.25 (3.61)	3.52 (3.66)	2.87 (3.62)
HADS D (0*-21)	6.04 (3.59)	5.64 (2.50)	6.48 (4.51)	2.81 (3.44)	1.89 (1.73)	3.78 (4.47)	2.28 (2.77)	2.00 (2.00)	2.67 (3.64)
EQ-5D-3L (-0.594-1*)	0.36	0.40	0.33	0.76	0.81	0.71	0.86	0.86	0.86
EQ-5D Health State (0-100*)	66.27	65.17	67.48	79.24 (18.48)	81.26 (16.75)	77.11 (20.42)	83.63	81.50	86.47
ICE-CAP-O (0-1*)	0.80	0.82	0.79	0.87	0.90	0.84	0.91	0.90	0.92

*Scale best outcome †including telephone collected minimum data set (n=3)

Table 4 Descriptive statistics by allocation (outcome measures)

Table 5 summarises the number of items missing from the returned Client Service Receipt Inventory resource use questionnaires. Missing data were most prevalent in the 'medication' and 'friends/relatives help at home' sections, whilst both the 'friends/relatives time off work' and 'current work situation' sections were mostly returned complete. Comparing the randomisation arms of the study, the greatest number of missing data were observed in the control group, in particular in the 'medication' and 'friends/relatives help at home' sections which have a considerably higher number of missing values than the same sections in the intervention group.

Question	Questions Missing (n)	
	Control	Intervention
Hospital resource use (A&E, Outpatient appointments, overnight stays)	12	13
Service use (e.g. GP, Physiotherapy)	16	11
Medication (type and payment)	51	26
Personal costs incurred for NHS/social services (e.g. transport, cleaning, child care)	23	16
Time off work	4	1
Friends/relatives help at home (how many hours of help needed for household tasks)	106	29
Friends/relatives time off work (how many hours taken off work to provide help)	1	1
Current work situation	3	0
Total	216	97

Table 5 Summary of resource use questionnaire missing responses

Discussion

This feasibility study confirmed that recruitment, randomisation of participants, and delivery of the intervention could be successfully achieved and that the receipt of the intervention, or allocation to the control, was acceptable to all participants. Although methods to reduce attrition should be considered, loss to follow up was still reasonable, which suggest that this trial design can be taken forward into a phase III definitive trial. The recruitment of patients was negatively influenced by a competing trial taking place at the same sites, therefore it is expected that a better rate of recruitment could be achieved in a future trial if this is taken into account. The rates of follow up were good, however there were high levels of missing data in some time points (four week) and outcome measures (Western Ontario and McMaster Universities Arthritis Index, Nottingham Extended Activities of Daily Living scale) indicating that the burden of assessment needs to be considered prior to further work. The health economic data collected using the Client Service Receipt Inventory form was poorly completed by participants so it would be worth exploring other methods or adaptations for collecting these data. Allocation concealment was maintained until all participants had completed the 26 week follow-up questionnaire. Due to the lower response rates at 4 and 12 weeks as a result of some questions contradicting hip precautions and changes, and altered domiciliary arrangements possibly affecting the 4 week questionnaire response rates, the 26 week time point should be used as the primary time point in any future study.

Of patients screened, 332 (68%) were identified as meeting inclusion criteria for the trial which represents a good rate of participant identification. Eighty four (74%) of the screened patients not meeting the inclusion criteria was due to previous or planned lower limb replacement. Of the 181 participants excluded due to 'other reasons', this was mainly due to 109 (60%) being eligible for the

competing trial (adopted prior to this study and therefore prioritised), and to a lesser extent, 58 (32%) having their surgery date brought forward precluding recruitment. The recruitment rate was 22% of eligible patients which is lower than the 48–85% recruitment rates reported in similar trials of rehabilitation relating to total hip replacement surgery^{[31][32][33]}. Retention of participants was good, with a follow-up return rate of 88% at 26 weeks, comparable with the 89 - 98% retention rates in similar clinical trials^{[34][35]}.

The proportion of fully completed questionnaires (64%) was slightly lower than noted in other trials^[36]; however, it is not unusual for this type of trial to have some missing outcome data^[37]. Several participants commented that the questionnaire pack was too long and repetitive. As one of the aims was to compare a number of outcome measures for suitability for a definitive trial, the participant burden of completing the questionnaire was anticipated. However, in a future trial, the questionnaire pack would need to be shorter which should result in higher rates of response^[38], and less missing data. The scales with the most missing questions across the four time points were Western Ontario and McMaster Universities Arthritis Index and Nottingham Extended Activities of Daily Living scale. The scales with the least amount of missing data were Hospital Anxiety and Depression Scale, ICECAP-O, EQ-5D-3L, and Oxford Hip Score. The proportion of missing data in the Western Ontario and McMaster Universities Arthritis Index and Nottingham Extended Activities of Daily Living scale compared to the other scales suggest that these may not be suitable for taking forward as outcome measures in a future definitive trial.

At 4 and 12 weeks, both the response rate and number of fully completed questionnaires was low. Some of the questions in the outcome measures conflicted with the routine hip precautions patients have to comply with after total hip replacements, e.g. not to bend more than 90° for six weeks after surgery or not to drive a car, and some participants' comments did suggest this was why they did

not complete some questions. Therefore, this may suggest that the 4 week follow up period or the scales used are not suitable for this and can explain higher rates of missing data on returned questionnaires. At the week 4 and 12 time points, telephone calls were made by the research team if the questionnaire was not returned by the expected date. At the 4 week follow-up, several participants could not be contacted. Abiding by the ethics agreement, the research team were unable to ask people why they were not completing the questionnaire, though some participants voluntarily commented they did not 'feel up to completing it' as they were more temporary disabled than they had anticipated, or they had made alternative living arrangements. Telephone, text message, or e-mails reminders should be instigated if a main randomised clinical trial is undertaken.

The Client Service Receipt Inventory health resource use questionnaire had both a poor rate of return, and completion, with only 15 (34%) of the 44 participants returning a correctly completed form, which is not unusual for health economic information^[39]. This suggests that for a future definitive trial, the Client Service Receipt Inventory form may need to be adapted to make it simpler to complete. Also, other methods should be considered such as resource use diaries which have been shown to increase the quality of data captured^[39], or sending more frequent questionnaires to capture data rather than asking people to recollect contact over 6 months.

The difference between the standard deviation (SD) between groups at baseline and 26 weeks ranged from 3% to 46% SD for all the outcomes measured. From data inspection, the potential intervention effect size was set at one third standard deviation difference between the two arms. The Oxford Hip Score is proposed to be the primary outcome measure to take forward, hence the power calculation based on the data from this feasibility study was conducted to estimate the minimum number of patients required to power a main study. With a 1-power= 80%, alpha=0.05 (two sided) and a 0.33 SD difference between arms, 68 subjects are needed per arm; thus a total

sample size of 136. As the feasibility study had a 12% attrition rate from baseline assessment to 26 week measurement, the number of participants giving consent would need to be increased to 166 to accommodate this rate of attrition.

This study had several strengths. It was conducted following the standard operating procedures of a major clinical trials unit who performed the randomisation and maintained the data in a secure bespoke database. Allocation concealment and outcome assessor blinding was maintained until point of analysis by following established procedures for rehabilitation trials. There were no participant withdrawals after allocation, no crossover from the intervention to control arm and all participants allocated received the occupational therapy intervention. We achieved our aim to deliver the occupational therapy intervention between 2 to 4 weeks before surgery which demonstrated the delivery of the intervention in both content and time of delivery is feasible. Despite competition from another large trial recruiting total hip replacement patients at the same recruitment sites, we successfully managed to screen, identify and recruit patients at an acceptable rate. The study had infrastructure support as it was adopted by both the primary care and musculoskeletal clinical research networks and was part of an NIHR programme grant. Throughout the trial, there were no deviations from protocol.

The main weaknesses of the trial are the rate of return of questionnaires and the amount of missing data in those returned; this was particularly so for the health resource usage data. This was partially as a consequence of the questionnaire being too long and repetitive, which will be need to be addressed in future.

Clinical messages

- This feasibility study has demonstrated that a fully powered randomised controlled trial of pre-operative occupational therapy for patients receiving total hip replacement is feasible.
- Pre-surgery occupational therapy assessments and interventions can be effectively delivered and were well received.

Acknowledgements

Firstly we would like to thank staff and patients at the Royal Orthopaedic Hospital NHS Foundation Trust, Birmingham, UK, and the Dudley Group of Hospitals NHS Foundation Trust, Dudley, UK, for their participation in this trial. We acknowledge the assistance of Karen Lett and Kerry Steel as the therapists that delivered the intervention. We also acknowledge the 'Patient Experience Partnership in Research' group at Southmead Hospital, Bristol, UK, who helped formulate the content of the intervention and the trial research nurses and data manager. Additionally, we would like to acknowledge Emma Costello who contributed to data collection and study management and Richard Gravelle who contributed to data entry and analysis and Erik Lenguerrand who provided statistical advice.

Funding:

This article presents independent research funded by the National Institute for Health Research (NIHR) in England under its Programme Grants for Applied Research programme [RP-PG-0407-10070]. The views expressed in this article are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

The research team acknowledge the support of the NIHR, through the Comprehensive Clinical Research Network.

Prof Sackley is also in possession of a NIHR Senior Investigator Award.

Contributors

Paul Jepson: Contributed to the design, administered and monitored the study. Wrote the protocol and obtained ethical approval. Undertook data collection and led data entry. Completed the final version article and contributed to the statistical analyses.

Gina Sands: Drafted the manuscript, led data analysis, contributed to study management and data collection.

Andrew Beswick: Provided intellectual advice on design, conduct, analysis and provided critical revisions of the manuscript.

Edward T Davis: Provided intellectual advice on design, conduct and provided critical revisions of the manuscript.

Ashley Blom: Provided intellectual advice on design, conduct and provided critical revisions of the manuscript.

Catherine M Sackley: Contributed to the design, conduct and analysis. Study guarantor and provided critical revisions of the manuscript.

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